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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,436	01/30/2002	Steve G. Baker	ENDOV-59271	5619

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EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,436

Applicant(s)

BAKER ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

In view of the appeal brief filed on June 6, 2005, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

The Applicant argues:

"It is respectfully submitted that combining the Rhodes and Lazarus et al. references under 103 is improper because there is no suggestion or motivation, nor an objective reason for the combination. It is particularly improper here since Rhodes is concerned with avoiding the shortcomings of self-expanding structures and specifically teaches a stent formed from rigid links or struts (Col. 6, ln. 33). The combination of teachings employed in the final Office action requires Rhodes to be modified to incorporate a self-expanding frame which is, in fact, the very characteristic Rhodes seeks to avoid."

Regarding motivation, the motivations (to serve as attachment means at each end of the graft and when implanted oppose migration of the graft) are found within Lazarus as noted in the rejection below.

Regarding the "shortcomings" cited by Rhodes, Rhodes concerns are directed towards stents, not necessarily towards stent-grafts. The stents Rhodes is concerned about are sleeve-like devices while the Lazarus device is a ring. In addition, the rings of Lazarus are designed to overcome some of these concerns. The Lazarus rings comprise "hook-like elements", that "should have a length which is sufficient for the hook to penetrate the vessel wall, but not through the vessel wall" (col. 9, lines 19-22). Furthermore, Rhodes states that his invention overcomes "the disadvantages of the prior art, e.g., can be used over long distances, for long segment occlusions in the vascular tree, while acting to prevent acute and chronic recurrence." The combination of Lazarus and Rhodes would still overcome the cited "disadvantages of the prior art."

The combination would not change the ***principal operation*** of the prior art invention being modified. The Rhodes reference would not require a substantial reconstruction and redesign of elements shown as well as a change in the basic principle under which the construction was designed to operate. Lazarus teaches (col. 14, lines 47-55):

"Because of the spring forces provided by the attachment means, it is possible that the grafts can be implanted without the use of an inflatable balloon for forcing the hook-like elements into the tissue of the vessel. However, at the present time, it is still believed to be desirable to utilize

the balloon to ensure that the hook-like elements are firmly implanted into the wall of the vessel so as to inhibit migration of the graft within the vessel."

Therefore, a self-expanding stent can still be expanded with a balloon and the device would still function as an endovascular bypass graft without substantial reconstruction or redesign of the elements shown.

In addition, Rhodes states that the method of use of the graft entails introducing it by utilizing "some means, e.g., disposing the sleeve on a conventional balloon catheter." This implies that other means are possible even though a balloon catheter is preferred.

The Applicant also compares the present rejection to In re Ratti as a further argument for "teaching away". However, unlike the Ratti decision, the "rigidity" of the device is not **required** for operation. The graft of Rhodes when combined with the ring of Lazarus would not change the **basic principle** under which the Rhodes construction is designed to operate.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24 and 26-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe "at least one of the plurality of frames being self-expandable." The specification discloses, "it is further contemplated that the center section of the graft be supported by one or more self-expanding attachment systems stacked end to end." However, these attachment systems are *in addition* to the two attachment systems (175, 176) at the ends of the graft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes (5,122,154) in view of Lazarus et al. (5,275,622). Rhodes discloses a graft comprising: a plurality of discrete non-overlapping frames (30) along its length, which may be inside the graft (col. 4, lines 19-22), have wall engaging members (col. 7, lines 18-30), and is pleated, which may provide a tapered profile (Fig. 6) however Rhodes fails to disclose a frame having a plurality of helical apices that extend beyond the length the graft, that have hooks as wall engaging members. Lazarus et al. teaches a graft comprising a self-expanding frame having a plurality of helical apices that extend beyond the length the graft, that have hooks as wall engaging members (Fig.11) to

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serve as attachment means at each end of the graft and when implanted oppose migration of the graft (col. 9, lines 60-62). It would have been obvious to one of ordinary skill in the art to combine the teaching of a graft comprising a frame having a plurality of helical apices that extend beyond the length the graft, that have hooks as wall engaging members, as taught by Lazarus et al., to a graft as per Rhodes, in order to serve as attachment means at each end of the graft and when implanted oppose migration of the graft.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized, flowing script.

Thomas Barrett
Examiner
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